Complete Summary

GUIDELINE TITLE

VHA/DoD clinical practice guideline for the management of dyslipidemia in primary care.

BIBLIOGRAPHIC SOURCE(S)

Veterans Health Administration, Department of Defense. VHA/DoD clinical practice guideline for the management of dyslipidemia in primary care. Washington (DC): Veterans Health Administration, Department of Defense; 2001 Dec. Various p. [115 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Dyslipidemia

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice

Internal Medicine
Nutrition

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To incorporate information from several existing national recommendations into a format which would facilitate clinical decision-making
- To improve local management of patients with dyslipidemia and thereby improve patient outcomes

TARGET POPULATION

Persons eligible for care in the U.S. Department of Defense (DoD) or Veterans Health Administration (VHA) health care delivery system

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment/Diagnosis

1. Patient history and assessment of risk factors
2. Measurement of total cholesterol and high-density lipoprotein (HDL) or total cholesterol (TC), high-density lipoprotein, triglycerides (TG), and low-density lipoprotein (LDL)
3. Fasting lipid profile, including low-density lipoprotein
4. Diagnosis of possible secondary causes of elevated low-density lipoprotein cholesterol using measurement of serum thyroid-stimulating hormone (TSH), blood urea nitrogen (BUN)/creatinine, and dipstick urinalysis
5. Diagnosis of possible secondary causes of hypertriglyceridemia by screening for alcohol use, reviewing dietary habits, and evaluating possible drug side effects (e.g., progestins, estrogens, androgens, anabolic steroids, corticosteroids, cyclosporine, and retinoids)

Management/Treatment

1. Age-appropriate lifestyle education on smoking, diet, and exercise
2. Treatment for secondary causes of elevated low-density lipoprotein cholesterol (LDL-C)
3. Treatment for secondary causes of hypertriglyceridemia
4. Medical nutrition therapy
5. Drug therapy (monotherapy or combination therapy), including HMG-CoA reductase inhibitors (statins), such as lovastatin, simvastatin, atorvastatin, fluvastatin and pravastatin; immediate-release niacin such as Niacor;

sustained-release niacin, such as Niaspan; bile acid resins, such as cholestyramine, and colestipol; or fibrates, such as fenofibrate and gemfibrozil
6. Addressing adherence to therapy
7. Repetition of dyslipidemia evaluation

MAJOR OUTCOMES CONSIDERED

- Total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol and triglyceride levels
- Risk of developing coronary heart disease
- Risk of developing atherosclerotic cardiovascular disease
- Response to lifestyle changes and therapy, such as dietary changes, exercise, weight reduction, smoking cessation, reduction of excessive alcohol, and drug therapy
- Adherence to diet, exercise and drug therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed a search using the National Library of Medicine's (NLM) MEDLINE database. The term "hyperlipidemia" was searched along with the following Boolean expressions AND terms:

- Epidemiology
- Screening
- Diagnosis
- Primary Care
- Protocols
- Therapy
- Patient Education
- Economics

Qualifiers dealing with specific types of publications (e.g., meta-analysis) were also used. Articles were also limited to English language only and those published between 1994 and 1999, with some exceptions.

The guideline also drew heavily from the following sources for recommendations:

- Executive summary of the Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA 2001 May 16;285(19):2486-97.
- NIH Consensus conference. Triglyceride, high-density lipoprotein, and coronary heart disease. NIH Consensus Development Panel on Triglyceride,

High-Density Lipoprotein, and Coronary Heart Disease. JAMA 1993 Jan 27;269(4):505-10.
- Guidelines for using serum cholesterol, high-density lipoprotein cholesterol, and triglyceride levels as screening tests for preventing coronary heart disease in adults. American College of Physicians. Part 1. Ann Intern Med 1996 Mar 1;124(5):515-7.
- U.S. Preventive Services Task Force. Screening for high blood cholesterol and other lipid abnormalities. In: Guide to clinical preventive services. 2nd ed; Baltimore (MD): Williams & Wilkins; 1996. p. 15-38.
- Pharmacy Benefits Management—Medical Advisory Panel. The pharmacologic management of hyperlipidemia. VHA PBM-SHG Publication. Hines (IL): Pharmacy Benefits Management Strategic Health Group, Veterans Health Administration, Department of Veterans Affairs, 1999.

NUMBER OF SOURCE DOCUMENTS

62 articles

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence Grading

I: Evidence is obtained from at least one properly randomized clinical trial (RCT).

II-1: Evidence is obtained from well-designed controlled trials without randomization.

II-2: Evidence is obtained from well-designed cohort or case-control analytical studies, preferably from more than one center or research group.

II-3: Evidence is obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940's) could also be regarded as this type of evidence.

III: Opinions of respected authorities are based on clinical experience, descriptive studies and case reports, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Sixty-two articles were identified for inclusion in a table of information that was provided to each expert participant. The table of information included title, author(s), author(s) affiliation, publication type, abstract, source, and relevance. Copies of these tables were made available to all participants. Copies of specific articles were provided on an as needed basis.

The working group reviewed the articles for relevance and graded the evidence using the rating scheme published by the U.S. Preventive Services Task Force (USPSTF, 1996).

The quality of evidence rating is based on the quality, consistency, reproducibility, and relevance of the studies. Information about harmful effects must also be presented. The strength of evidence rating is influenced primarily by the science. Other factors that are taken into consideration when making a strength of evidence determination are the burden of suffering, cost issues, and policy concerns. For many recommendations, there is insufficient evidence to determine whether or not routine intervention will improve clinical outcomes. Lack of evidence of effectiveness does not mean there is evidence of ineffectiveness. Rather, lack of evidence (strength of recommendation = C) means insufficient statistical power, unrepresentative populations, lack of clinically important endpoints, or design flaws.

The experts themselves, after an orientation and tutorial on the evidence grading process, formulated quality of evidence and strength of recommendation ratings. Each reference was appraised for scientific merit, clinical relevance, and applicability to the populations served by the Federal health care system. Recommendations were based on consensus of expert opinions and clinical experience only when scientific evidence was unavailable.

The assembled experts were an invaluable source of additional information and suggested numerous references. These were distributed to participants on an as needed basis. It must be noted that the guideline document does not, however, include reference to any publication dated after December 1999.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The current guideline for the management of dyslipidemia represents hundreds of hours of diligent effort on the part of participants from the Department of Defense (DoD), Veterans Health Administration (VHA), academia, and a team of private guideline facilitators. An experienced moderator facilitated the multidisciplinary panel that included internists, family practitioners, cardiologists, nurses, pharmacists, medical nutrition therapists, and rehabilitation specialists. Policy-makers and civilian practitioners joined these experts from the DoD and VHA. The process is evidence-based whenever possible. Where evidence is ambiguous or conflicting, or where scientific data are lacking, the clinical experience within the room was used to guide the development of consensus-based recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The rating scheme used for this guideline is based upon a system used by the U.S. Preventive Services Task Force (USPSTF, 1996). The scheme is as follows:

Strength of Recommendation Grading:

A. There is good evidence to support the recommendation that the condition be specifically considered.
B. There is fair evidence to support the recommendation that the condition be specifically considered.
C. There is insufficient evidence to recommend for or against the inclusion of the condition, but recommendations may be made on other grounds.
D. There is fair evidence to support the recommendation that the condition be excluded from consideration.
E. There is good evidence to support the recommendation that the condition be excluded from consideration.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the management of dyslipidemia in the primary care setting are organized into 3 major algorithms. Each algorithm, the objectives and annotations that accompany it, and the evidence supporting the recommendations are presented below. The strength of recommendation grading (A-E) and quality of evidence grading (I-III) are defined at the end of the "Major Recommendations" field.

Primary Care Screening Algorithm

Primary Prevention Algorithm

Secondary Prevention Algorithm

Note: A list of all abbreviations is provided at the end of the "Major Recommendations" field.

A. Adult Patient Enrolled in the Health Care System

Definition

Any Adult (> age 17) who is eligible for care in the Department of Defense (DoD) or Veterans Health Administration (VHA) health care delivery system should be screened for dyslipidemia as described in this guideline.

B. Obtain History. Assess Risk Factors for Atherosclerotic Cardiovascular Disease (ASCVD)

Objective

To identify clinical markers that predict an increased risk for developing ASCVD, thereby changing the interpretation of LDL levels.

Annotation

A high low-density lipoprotein (LDL) cholesterol level is a strong predictor of cardiovascular (CV) risk, although in the absence of other CV risk factors the absolute risk for developing ASCVD is still relatively low. Conversely, the presence of other recognized coronary heart disease (CHD) risk factors magnify the risk associated with any level of LDL. Proven, independent, clinical predictors of increased risk for ASCVD (in addition to elevated LDL cholesterol) include:

1. Age (males > 45 years, females > 55 years or menopause < age 40?)
2. Family history of premature coronary artery disease; definite myocardial infarction (MI) or sudden death before age 55 in father or other male first-degree relative, or before age 65 in mother or other female first-degree relative
3. Current cigarette smoker
4. Hypertension (systolic blood pressure $\geq$ 140 mmHg or diastolic blood pressure $\geq$ 90 mmHg confirmed on more than one occasion, or current therapy with antihypertensive medications)
5. Diabetes mellitus (DM)
6. High-density lipoprotein (HDL)-cholesterol < 40 mg/dL

"Negative" Risk Factor

Elevated HDL cholesterol, > 60 mg/dL, is a well-established independent, clinical predictor of decreased risk for ASCVD. It has been suggested that an HDL > 60 mg/dL negates one ASCVD risk factor for individual risk calculation.

Evidence

LDL: Quality of Evidence=I; Strength of Recommendation=A (Multiple Risk Factor Intervention Trial [MRFIT], 1982; Neaton & Wentworth, 1992; Castelli, 1984).

HDL: Quality of Evidence=II-2; Strength of Recommendation=A (Gordon, Probstfeld, & Garrison, 1989; Downs et al., 1998; Wilson, Abbott, & Castelli, 1988; Kannel, 1978).

C. Does Patient Have a History of ASCVD?

Objective

Prompt identification of patients known to benefit from lipid lowering therapy.

Annotation

All patients with known CHD (history of myocardial infarction [MI], angina pectoris, other evidence of CHD) or a history of other kinds of vascular disease (such as stroke or claudication) are at high risk for coronary events. Prevention of recurrent and fatal coronary events via aggressive lipid-lowering therapy has been demonstrated in large clinical trials.

D. Is Patient Younger than 35 Years or Older than 75 Years?

Objective

To screen the segment of the beneficiary population most represented in randomized controlled trials of hyperlipidemia intervention.

Annotation

At a population level, patients of any age may benefit from general lifestyle recommendations to curtail dietary saturated fat and to perform aerobic exercise several times per week, regardless of the results of lipid screening. Targeted lipid screening of males aged 35 to 75 years and females aged 45 to 75 years is recommended in the primary prevention setting, based on the results of RCTs of lipid interventions. For every given age, the ASCVD risk for a female is the same as that for a male 10 years her junior.

The recommendation for screening up to age 65 is based on strong clinical and epidemiologic evidence. The recent AFCAPS/TexCAPS (Air Force/Texas Coronary Atherosclerosis Prevention Study) trial results (Downs et al., 1998) suggest that treating patients age 65-73 is beneficial. Epidemiologic evidence suggests benefit in ages 65 to 75. The association of cholesterol and mortality weakens in elderly patients, and screening is not recommended for primary prevention after age 75.

The risk of ASCVD is so low in males younger than 35 years and females younger than 45 years that screening cannot be recommended unless there is an unusual family history of coronary events occurring prior to age 45.

E. Provide Age-Appropriate Lifestyle Education on Smoking, Diet, and Exercise

Objective

To promote lifestyle changes that will decrease the risk of ASCVD.

Annotation

Smoking, diet, and activity level are important modifiable predictors of risk for ASCVD (McGinnis & Foege, 1993). Primary care clinicians can have a positive effect on health behaviors and should provide and/or arrange for age-appropriate lifestyle education. The top three lifestyle behaviors associated with premature death are:

> Risk: Smoking
> Recommended Intervention: Advise smokers/tobacco users to quit.
>
> Risk: Diet
> Recommended Intervention: Provide basic information about managing a healthy diet (using the U.S. Department of Agriculture Dietary Guidelines for Americans, 1992).
>
> Risk: Sedentary lifestyle
> Recommended Intervention: Encourage 30 minutes or more of moderate intensity activity on most days of the week.

Many experts also recommend attention to the following additional lifestyle modifications:

- Limitation of alcohol intake to one or two drinks per day
- Reduced calorie diet to promote weight loss, if overweight
- Stress management

Evidence

Smoking: Quality of Evidence=I; Strength of Recommendation=A (U.S. Department of Health and Human Services [USDHHS], 1989; National Cancer Institute [NCI], 1994; Ockene, 1987; Ockene et al., 1991; Fiore, 1994).

Diet: Quality of Evidence=I; Strength of Recommendation=A (U.S. Preventive Services Task Force [USPSTF], 1996; Beresford et al., 1997; McCarron et al., 1997).

Exercise: Quality of Evidence=I; Strength of Recommendation=A (Pate et al., 1995; American College of Sports Medicine [ACSM], 1995; Pollock & Wilmore, 1990; Spate-Douglas & Keyser, 1999).

Lifestyle changes promote general health: Quality of Evidence=III; Strength of Recommendation=A (Executive Summary of the third report of the National Cholesterol Education Program [NCEP III], 2001).

Changing behavior is very difficult: Quality of Evidence=I; Strength of Recommendation=A (Ebrahim, Davey, & Smith, 1999).

F. Does Patient Have Diabetes Mellitus?

Objective

To promote the prompt identification and aggressive management of lipid disorders identified in patients known to be diabetic.

Annotation

- Patients with DM are at significantly increased risk of CHD compared with non-diabetic patients of similar age.
- DM patients without known CHD appear to have a risk for first MI similar to the risk for recurrent MI of non-DM patients with CHD and a prior coronary event.
- Patients with type 2 diabetes commonly have other risk factors (hypertension, high LDL-C, low HDL-C, obesity) that increase risk for cardiac events.

Evidence

Diabetes is an independent risk factor: Quality of Evidence=II-2; Strength of Recommendation=B (MRFIT, 1982; Neaton & Wentworth, 1992; Stamler et al., 1993; Haffner et al., 1998).

Management of "diabetic dyslipidemia": Quality of Evidence=I; Strength of Recommendation=A (Rubins et al., 1999).

G. Obtain Total Cholesterol (TC) and HDL or TC, HDL, TG, LDL

Objective

To risk-stratify patients for targeted intervention versus follow-up screening.

Annotation

Lipid levels may be obtained in a fasting or nonfasting state. TC levels and HDL-C can be measured in the nonfasting patient. TG concentrations, however, are affected by recent food intake and will affect the calculation of LDL-C by the Friedewald equation: LDL-C = [TC] - [HDL-C] - [TG/5].

Nonfasting values differ from fasting values, but may still provide useful—though more limited—information. It may be inconvenient for the patient to return for a fasting sample. Costs may vary depending on which lipids (TC, HDL, LDL, VLDL, TG) are requested. At many institutions, a panel is available.

Clinical decisions should be based on two lipid profiles, done 1 to 8 weeks apart, which have an LDL-C or TC difference of < 30 mg/dL.

Recent myocardial infarction, stroke, surgery, trauma, or infection may transiently lower cholesterol levels up to 40 percent. If a lipid profile cannot be obtained immediately (within 12 to 24 hours of the event), one must wait

8 weeks post-event to obtain an accurate reading. Cholesterol levels increase by as much as 20 to 35 percent during pregnancy and should not be measured until three to four months after delivery.

H. Reinforce Lifestyle Education, Smoking, Diet, and Exercise

Refer to Annotation E.

I. Repeat Dyslipidemia Evaluation in 1 to 5 Years

Objective

To provide appropriate clinical follow-up for patients at initially low risk for ASCVD.

Annotation

If the initial dyslipidemia screening reveals total cholesterol < 200 mg/dL or LDL cholesterol < 130 mg/dL AND HDL cholesterol > 35 mg/dl, the patient—in the absence of other risk factors—will be of average or below average risk for atherosclerotic events over a five-year period.

Because total and LDL cholesterol tend to increase with advancing age, patients at initially average risk for ASCVD events may over time become patients at above-average risk or may develop concurrent health conditions (nephrotic syndrome, hypothyroidism, diabetes mellitus) that can declare as dyslipidemia. Re-assessment of serum cholesterol and HDL five years after an initially favorable dyslipidemia screening permits timely identification and treatment of such individuals.

Evidence

Appropriate follow-up: Quality of Evidence=III; Strength of Recommendation=A (NCEP III, 2001; Lovastatin Study Groups, 1993; Jones et al., 1991).

J. Is Lipid Profile Abnormal?

Objective

To identify a group of patients who require further evaluation and/or therapy for hyperlipidemia.

Annotation

Patients with the following results of lipid measurements will require therapy for a lipid disorder:

- LDL > 130 mg/dL
- HDL < 40 mg/dL

- TG > 400 mg/dL

K. Repeat Dyslipidemia Evaluation in 1 to 2 Years

Objective

To provide appropriate clinical follow-up.

Annotation

If the initial dyslipidemia screening reveals total cholesterol > 200 mg/dL but fasting LDL cholesterol < 130 mg/dL AND HDL cholesterol > 40 mg/dL, the patient will be of average risk for lipid-related events over a one to two year period.

L. Evidence of Familial Disorder that Complicates Treatment?

Objective

To promote the prompt identification and aggressive lipid management that is indicated for this group.

Annotation

Most severe forms of hypercholesterolemia are the result of genetic disorders. Familial hypercholesterolemia is characterized by severe elevations of LDL cholesterol (> 260 mg/dL), tendon xanthomas, and premature CHD. Familial combined hyperlipidemia is characterized by elevations of total cholesterol, triglycerides, or both, in different members of the same family, and is associated with premature CHD. Patients presenting with very severe hypercholesterolemia should undergo family screening to detect other candidates for therapy. Therefore, a consultation with a specialist is recommended to assist the primary care clinician in co-managing these patients.

M. Consider and Treat Secondary Causes of Elevated LDL-C

Objective

To detect and, if needed, to treat health disorders that present as an elevated LDL-C.
Note: If a patient has hypertriglyceridemia, see Annotation N.

Annotation

Hypothyroidism, chronic renal failure, and the nephrotic syndrome are well known to cause elevated LDL-C. Recognition of these conditions will focus attention on a potentially treatable underlying disorder. Cost-effective screening of the patient presenting with hypercholesterolemia might therefore include measurement of serum thyroid-stimulating hormone (TSH), BUN/creatinine, and a dipstick urinalysis, to exclude these relatively common conditions. See Table 1 titled "Address Secondary Causes of Lipid

Abnormalities" in the original guideline for the effects of various disorders of lipid levels and suggested laboratory tests for diagnosis of these disorders.

Evidence

Address secondary causes: Quality of Evidence=III; Strength of Recommendation=A (Stone, 1997; NCEP III, 2001).

N. Consider and Treat Secondary Causes of Hypertriglyceridemia

Objective

To identify and address the secondary causes of hypertriglyceridemia.
Note: If patient has elevated LDL, see Annotation M above.

Annotation

The most common secondary causes of hypertriglyceridemia are alcohol, diabetes, and hypothyroidism. Addressing these underlying conditions can improve or normalize triglyceride levels, and failure to address these can render therapy ineffective.

O. Is TG > 400 mg/dL?

Objective

To identify patients for whom LDL-C calculation is not reliable.

Annotation

The Friedwald LDL calculation [LDL-C = total cholesterol - (HDL-C + TG/5)] yields unacceptably inaccurate estimation of the LDL cholesterol in patients with triglycerides > 400. There are other means to measure atherogenic cholesterol in this setting. Non-HDL cholesterol can be estimated using the simple formula [Non-HDL cholesterol = Total cholesterol – HDL] or by direct measurement of the LDL.

P. Is TG > 1000 mg/dL? Evaluate and Treat as Indicated

Objective

To identify and treat patients with extreme levels of triglycerides.

Annotation

Patients with triglycerides >1,000 are at increased risk of pancreatitis.

Treatment of Hypertriglyceridemia (TG >1000 mg/dL)

First Choice: Fibrates

Alternative: Niacin

Remarks: Fibrates are contraindicated in severe renal disease. Niacin is contraindicated in hepatic disease and relatively contraindicated in DM, gout, and history of complicated/active peptic ulcer disease (PUD).

Evidence

Treat extreme levels of triglycerides: Quality of Evidence=III; Strength of Recommendation=A (Piolot et al., 1996; NCEP III, 2001).

Q. Initiate Medical Nutrition Therapy (MNT) and Exercise

Objective

To reduce TG level with non-pharmacological therapy.

Annotation

For those individuals with elevated TG, the clinician should initiate MNT and appropriate exercise program. See Appendix 1, MNT, and Appendix 2, Exercise, of the original guideline document.

Evidence

MNT: Quality of Evidence=III; Strength of Recommendation=A (National Institutes of Health [NIH] Consensus Conference, 1993).

Exercise: Quality of Evidence=III; Strength of Recommendation=A (NIH Consensus Conference, 1993; Pate et al., 1995; Joint British recommendations, 1998).

R. Is LDL-C > 160 mg/dL (Estimated Non-HDL-C > 190)?

Objective

To identify patients who may need therapy for hypercholesterolemia.

Annotation

Patients with LDL cholesterol > 130 who have two or more atherosclerotic risk factors (other than cholesterol) or diabetes mellitus have significant risk of coronary or peripheral vascular events. Multiple prospective intervention trials have consistently demonstrated reduction in atherosclerotic event rates with treatment of hypercholesterolemia. In patients with known CHD (secondary prevention), the reduction in clinical endpoints is particularly compelling based on the demonstration of mortality benefit in some studies.

Evidence

LDL > 160 (Primary Prevention): Quality of Evidence=I; Strength of Recommendation=A (Downs et al., 1998; Frick et al., 1987; Lipid Research Clinics Program, 1984; Shepherd et al., 1995; NCEP III, 2001).

S. Determine Goal of Therapy; Initiate/Modify Therapy to Achieve Goal

Objective

To select an appropriate therapy based on LDL-C baseline level and other risk factors for ASCVD.

0. Select an appropriate LDL-C target
1. Initiate nonpharmacologic therapy
2. For patients who do not reach LDL target, initiate pharmacotherapy.

Annotation

Treatment should be based on LDL-C and CHD risk. CHD risk factors are age, family history, current smoker, hypertension, diabetes, and HDL-C < 40 mg/dL. Patients with CHD or multiple risk factors require more aggressive treatment. The goals for therapy and treatment are summarized below and in Table 3a and 3b in the original guideline document.

LDL-C Thresholds for Initial Dyslipidemia Treatment Based on Risk for ASCVD (Note: If one risk factor is diabetes, the diabetes category is used to determine threshold and category)

Known CHD

Baseline LDL-C [mg/dL] > 100: Diet/exercise; consider drug

Baseline LDL-C [mg/dL] > 130: Diet/exercise + drug

Baseline LDL-C [mg/dL] > 160: Diet/exercise + drug

Baseline LDL-C [mg/dL] > 190: Diet/exercise + drug

Diabetes (without known CHD)

Baseline LDL-C [mg/dL] > 100: Diet/exercise; consider drug

Baseline LDL-C [mg/dL] > 130: Diet/exercise + drug

Baseline LDL-C [mg/dL] > 160: Diet/exercise + drug

Baseline LDL-C [mg/dL] > 190: Diet/exercise + drug

No known CHD but > 2 risk factors

Baseline LDL-C [mg/dL] > 100: No treatment

Baseline LDL-C [mg/dL] > 130: Diet/exercise

Baseline LDL-C [mg/dL] > 160: Diet/exercise + drug

Baseline LDL-C [mg/dL] > 190: Diet/exercise + drug

No known CHD but < 2 risk factors

Baseline LDL-C [mg/dL] > 100: No treatment

Baseline LDL-C [mg/dL] > 130: No treatment

Baseline LDL-C [mg/dL] > 160: Diet/exercise

Baseline LDL-C [mg/dL] > 190: Diet/exercise + drug

LDL-Cholesterol Goals in the Treatment of Dyslipidemia Based on Risk for ASCVD

Known CHD: <120 mg/dL*

Diabetes (without known CHD): <120 mg/dL*

No known CHD, but > 2 risk factors: <130 mg/dL

No known CHD, but < 2 risk factors: <160 mg/dL

*NCEP III recommends an LDL-C goal of < 100 mg/dL in patients with known CHD and CHD equivalents (i.e., type 2 diabetes mellitus)

Non-Pharmacologic Therapy

Lifestyle change is indicated in all patients with 2 risk factors and LDL > 130mg/dL (> 100 mg/dL for known CHD or diabetes). Strategies include diet, exercise, smoking cessation, cessation of excessive alcohol, and weight control.

For primary prevention of ASCVD, patients whose initial treatment is diet/exercise should be given three to six months on dietary therapy prior to beginning medication, and longer if lipids are improving and nearing LDL thresholds. Patients failing clinician-initiated efforts may benefit from a MNT consult prior to initiating medications (See Appendix 1 titled "Medical Nutrition Therapy" of the original guideline document). The expected response to diet therapy is summarized below and in Table 4 of the original guideline. For secondary prevention of recurrent ASCVD events, non-pharmacologic therapy is always indicated, but should not delay appropriate pharmacotherapy.

Expected Percent Change in Serum Lipids in Response to Diet Therapy

LDL

Step I Diet -- -5 to -20%

Step II Diet -- -10 to -25%

Very Low Fat -- -0 to -20%

High MUFA[a] -- -5 to -20%

TG

Step I Diet -- +5 to -10%

Step II Diet -- +10 to -10%

Very Low Fat -- Decrease with weight loss; increase without weight loss

High MUFA[a] -- No change or slight decrease

[a]MUFA = Monounsaturated fatty acids.

Pharmacologic Therapy

Drug therapy is indicated in CHD/ASCVD patients and moderate-high risk primary prevention patients who remain above LDL thresholds with non-pharmacologic measures. HMG-CoA reductase inhibitors (statins) are first line agents in most situations. They are cost-effective in secondary prevention and high-risk primary prevention risk groups. The dose should be adjusted at 4 to 6 week intervals until the individually-determined LDL-C goals are met. Other agents have been shown to reduce CHD events and angiographic progression, but have had minimal impact on total mortality. The first line drugs and alternatives for lipid disorders are summarized below and in Table 5 of the original guideline document.

Dyslipidemia Drug Therapy Recommendations Based on Lipid Disorder

Lipid Disorder: Elevated LDL-C

<u>Initial monotherapy: Statins</u>

Efficacy: LDL -22 to -60%

Considerations: Caution using statins in hepatic disease

<u>Alternate monotherapy: Niacin</u>

Efficacy: LDL -13 to -21%

Considerations: Niacin is contraindicated in hepatic disease and relatively contraindicated in DM, gout, and history of complicated/active PUD;

Alternate monotherapy: Bile acid resin (resin)

Efficacy: LDL -10 to -20%

Considerations: Resins may increase TG

Lipid Disorder: Elevated LDL-C and Elevated TG

Initial monotherapy: Niacin

Efficacy: LDL -13 to -21%; TG -10 to -24%

or

Initial monotherapy: Statin

Efficacy: LDL -22 to -60%; TG -06 to -37%

Alternate monotherapy: Fibrates

Efficacy: LDL +10 to -35%; TG -32 to -53%

Considerations: For high TG, use fibrates or niacin; for high LDL, use statins

Lipid Disorder: Elevated LDL and Decreased HDL

Initial monotherapy: Niacin

Efficacy: LDL -13 to -21%; HDL +10 to +24%

or

Initial monotherapy: Statin

Efficacy: LDL -22 to -60%; HDL +2 to +12%

or

Initial monotherapy: Fibrates

Efficacy: LDL +10 to -35%; HDL +2 to +34%

Considerations: No preferences in terms of efficacy

Lipid Disorder: TG 400-1000 mg/dL

Consider gemfibrozil if HDL-C < 40 mg/dL

For high TG, use direct LDL-C measurement or non-HDL-C as lipid disorder to guide therapy

For CHD/ASCVD Patients

For patients with known CHD/ASCVD who have HDL < 40 mg/dL pharmacotherapy with gemfibrozil is recommended:

LDL-C < 130 mg/dL and HDL-C < 40 mg/dL

Efficacy: LDL +10 to –35%; HDL +2 to 34%

Considerations: Outcome data for secondary prevention only

Evidence

Lifestyle education: Quality of Evidence=I; Strength of Recommendation=A (Wilson et al., 1998; Ebrahim, Davey, & Smith, 1999).

Primary prevention: Quality of Evidence=I; Strength of Recommendation=A (Downs et al., 1998; Shepherd et al., 1995).

Secondary prevention: Quality of Evidence=I; Strength of Recommendation=A (Scandinavian Simvastatin Survival Study Group (4S), 1994; Leng, Price, & Jepson, 1999; NCEP III, 2001; Sacks et al., 1996; Frick et al., 1987; Canner et al., 1986; Post Coronary Artery Bypass Graft [CABG] Trial Investigators, 1997).

Treatment of low HDL: Quality of Evidence=1; Strength of Recommendation=A (Gordon, Probstfeld, & Garrison, 1989; Rubins et al., 1999).

T. Follow Up, Repeat Lipid Evaluation at Least Annually

Objective

To assure that patients initially treated for dyslipidemia receive periodic reassessment of the efficacy of treatment.

Annotation

When dyslipidemia is identified and the care provider and patient undertake dietary and/or pharmacologic treatment, it is pertinent clinically and economically to periodically repeat measurement of serum lipids to ensure that initially desirable response to therapy continues. Total and LDL cholesterol tend to increase with advancing age, even in intensively treated patients. Thus, an initially favorable response to treatment may not be maintained over time.

Evidence

Periodic follow up: Quality of Evidence=III; Strength of Recommendation=B (NCEP III, 2001).

U. Address Adherence to Therapy

Objective

To address patient adherence to diet, exercise, and drug therapy.

Annotation

Patients should be questioned about adherence to treatment at each visit. A minimum of three to six months of intensive diet and exercise is recommended before medications are initiated for primary prevention. Shorter trials of MNT and exercise are appropriate for patients with severe hyperlipidemia or ASCVD, since aggressive drug therapy is of demonstrated efficacy in these high risk groups.

Reasons for medication noncompliance include the following:

0. Medication side effects: Particularly an issue for niacin and resins, although statins may cause myalgias and nonspecific gastrointestinal symptoms.
1. Incomplete patient education: Patients may not understand benefit of medication or need for long-term therapy.
2. Cost: Patients may not be able to afford medications.

Reasons for diet and exercise noncompliance include the following:

3. Incomplete patient effort and self-motivation: Some patients are unable or unwilling to comply with strict dietary changes, such as a Step II diet, and a regular exercise regimen.
4. Suboptimal social support: Family and lifestyle may not be conducive to strict dietary changes. Patients may not have access to exercise facilities or safe environment (e.g., safe neighborhood in which to walk).
5. Incomplete patient education: Some patients may not have received adequate information because of missed visits or inadequate time for counseling.
6. Cost: Patients may perceive that dietary interventions increase costs, though this is generally not the case. Patients unable to walk may not have access to other exercise options (swimming, stationary bike/machines, etc.).

V. Modify Drug Therapy; Consider Combination Therapy

Objective

To modify drug therapy to achieve LDL-C goal.

Annotation

Niacin and resins are considered alternative therapy in patients who do not tolerate initial therapy. If the patient has not achieved the LDL-C goal with initial therapy, consider the addition of a second agent. Clinical judgment must be used to balance patient issues, side effects, and monitoring parameters.

W. Reschedule Lipids Evaluation at Appropriate Time and Follow Up until Goal Met

Objective

To assure that the efficacy of prescribed therapy of hyperlipidemia is measured after allowing sufficient time to reach a new steady state.

Annotation

Nadir values of LDL cholesterol and triglycerides may not be achieved until after three to six months on a Step I or Step II diet. Pharmacotherapy likewise may not result in lower lipid values until after at least one month of treatment. Remeasurement of serum lipids after at least one month of drug therapy, or after at least three months of dietary therapy, allows for the documentation of efficacy, the identification of unfavorable effects of treatment, and the dose titration of medication.

X. Is LDL-C > 130 mg/dL or HDL-C < 40 mg/dL?

Objective

To identify patients with ASCVD who are candidates for aggressive treatment of hypercholesterolemia.

Annotation

Patients with known ASCVD (secondary prevention) have significant risk of coronary or peripheral vascular events and are therefore candidates for aggressive lipid management. Multiple prospective intervention trials have consistently demonstrated reduction in atherosclerotic event rates with treatment of hypercholesterolemia. For this group, the reduction in clinical endpoints is particularly compelling, based on the demonstration of mortality benefit in some studies. In the major clinical trials published to date, actual LDL-C attained with statin therapy has ranged between 98 mg/dL and 118 mg/dL. As noted above and in Table 3 of the original guideline document, the target lipid levels in secondary CHD prevention are:

- LDL-C < 120 mg/dL* and
- HDL-C > 40 mg/dL.

*NCEP III and the American Diabetes Association guidelines support initiation of LDL-lowering therapy for patients with LDL in the 100-130 mg/dL range. Absolute risk reduction in CHD events for drug treatment initiated at this

threshold has not yet been established, except in the setting of HDL-C < 40 mg/dL (VA-HIT Study, 1999).

In the VA-HIT Study, the average LDL-C of treated patients was 112 mg/dL and the average HDL-C was 33 mg/dL.

Evidence

Aggressive treatment for patients with known ASCVD: Quality of Evidence=I; Strength of Recommendation=A (Post CABG Trial Investigators, 1997; Sacks et al., 1996; Long-Term Intervention with Pravastatin in Ischemic Disease Study Group [LIPID], 1998; Rubins et al., 1999).

Y. Repeat Evaluation in 1 to 2 Years as Indicated

Objective

To assure that patients with CAD risk factors other than hyperlipidemia are carefully monitored for onset of hyperlipidemia.

Annotation

Because total and LDL cholesterol tend to increase with advancing age, patients with initially borderline LDL values may evolve frankly elevated LDL with the passage of 1 year, or may develop concurrent health conditions (nephrotic syndrome, hypothyroidism, diabetes mellitus) that can declare as hyperlipidemia. Patients known to be at high risk for CAD based on multiple risk factors other than hyperlipidemia are candidates for early and aggressive dietary and pharmacologic therapy; thus annual reevaluation of serum lipid status is prudent and cost-effective.

Strength of Recommendation:

A. There is good evidence to support the recommendation that the condition be specifically considered.
B. There is fair evidence to support the recommendation that the condition be specifically considered.
C. There is insufficient evidence to recommend for or against the inclusion of the condition, but recommendations may be made on other grounds.
D. There is fair evidence to support the recommendation that the condition be excluded from consideration.
E. There is good evidence to support the recommendation that the condition be excluded from consideration.

Quality of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytical studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

Abbreviations

AIDS – Acquired immune deficiency syndrome

ASCVD – Atherosclerotic cardiovascular disease

CAD – Coronary artery disease

CHD – Coronary heart disease

CV – Cardiovascular

DM – Diabetes mellitus

HbA1c – Glycosylated hemoglobin

HDL – High-density lipoprotein

HDL-C – High-density lipoprotein-cholesterol

HIV – Human immunodeficiency virus

HMG-CoA – HMG CoA reductase inhibitors

LDL – Low-density lipoprotein

LDL-C – Low-density lipoprotein-cholesterol

LFT – Liver function test

MI – Myocardial infarction

MNT – Medical nutrition therapy

MUFA – Monounsaturated fatty acids

PUD – Peptic ulcer disease

RCT – Randomized controlled trial

Scr – Serum creatinine

TC – Total cholesterol

TG – Triglycerides

TSH – Thyroid-stimulating hormone

VLDL – Very-low density lipoprotein

CLINICAL ALGORITHM(S)

Algorithms are provided for:

- Primary Care Screening Algorithm
- Primary Prevention Algorithm
- Secondary Prevention Algorithm

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The annotations which accompany the algorithms in the guideline document indicate whether each recommendation is based on scientific data or expert opinion. Where existing literature is ambiguous or conflicting, or where scientific data are lacking on an issue, recommendations are based on the expert panel's opinion and clinical experience. The reference list at the end of each annotation includes all the sources used -- directly or indirectly -- in the development of the annotation text. A complete bibliography is provided at the end of the document.

The quality of the evidence supporting the recommendations are given for selected recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Dyslipidemia is a major risk factor for coronary heart disease and atherosclerotic cardiovascular disease and its subsequent morbidity and mortality. Lipid-related interventions, including lifestyle modifications, such as diet and exercise, and drug therapy can reduce the risk of atherosclerotic cardiovascular disease in patients with high cholesterol.

Subgroups Most Likely to Benefit:

Patients at increased risk for atherosclerotic cardiovascular disease, including:

- Patients with high levels of total cholesterol
- Patients with high levels of low-density lipoprotein cholesterol (LDL-C)
- Patients with low levels of high-density lipoprotein cholesterol (HDL-C) (<40 mg/dL)
- Male patients
- Older patients (males >45 years; females >55 years or menopause <age 40)
- Patients with high blood pressure (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg confirmed on more than one occasion, or current therapy with antihypertensive medications
- Patients who use tobacco
- Patients with diabetes mellitus
- Patients with a family history of premature coronary heart disease; definite myocardial infarction or sudden death before age 55 in father or other male first-degree relative, or before age 65 in mother or other female first-degree relative

POTENTIAL HARMS

- Statins may increase alanine aminotransferase (ALT) levels in 0.1-1.9% of patients.
- Resins may increase triglycerides.
- There is a risk of myopathy when statins are used in combination with gemfibrozil or niacin therapy. The niacin or statin product selected, as well as the dose of the statin, may affect the risk for myopathy.
- Warfarin doses may need to be adjusted to avoid bleeding complications in patients on gemfibrozil therapy.
- There are significant drug interactions noted with bile acid resins, fibrates, niacin, and statins. See Appendix 3 in the original guideline document for a list of known drug interactions to date.

Subgroups Most Likely to be Harmed:

- Clinicians should use caution when using statins in patients with hepatic disease and in patients with severe renal impairment.
- Resins should be used with caution in patients with active peptic ulcer disease due to gastrointestinal irritation.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Niacin is contraindicated in patients with hepatic disease and relatively contraindicated in patients with diabetes mellitus, gout, and history of complicated/active peptic ulcer disease.
- Fibrates are contraindicated in hepatic disease.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The guideline is designed to be adapted to an individual facility's needs and resources. The guideline will also be updated periodically or when relevant research results become available. The guideline should be used as a starting point for innovative plans that improve collaborative efforts and focus on key aspects of care.
- The use of this guideline must always be considered as a recommendation within the context of a provider's clinical judgment in the care for an individual patient.
- The clinical practice guideline is presented in an algorithmic format. A clinical algorithm is a set of rules for solving a clinical problem in a finite number of steps. It allows the practitioner to follow a linear approach to the recognition and treatment of dyslipidemia. It is recognized, however, that clinical practice often requires a nonlinear approach, and must always reflect the unique clinical issues in an individual patient-provider situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Veterans Health Administration (VHA) instituted performance measures for implementation of clinical practice guidelines in fiscal year 1998. These measures included screening for lipid abnormalities in diabetic patients with established coronary heart disease. Along with the work in the current guideline itself, both the Veterans Health Administration and the Department of Defense (DoD) are developing additional performance measures.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Veterans Health Administration, Department of Defense. VHA/DoD clinical practice guideline for the management of dyslipidemia in primary care. Washington (DC): Veterans Health Administration, Department of Defense; 2001 Dec. Various p. [115 references]

ADAPTATION

This guideline drew heavily from the following sources:

- Executive summary of the Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA 2001 May 16;285(19):2486-97.
- NIH Consensus conference. Triglyceride, high-density lipoprotein, and coronary heart disease. NIH Consensus Development Panel on Triglyceride, High-Density Lipoprotein, and Coronary Heart Disease. JAMA 1993 Jan 27;269(4):505-10.
- Guidelines for using serum cholesterol, high-density lipoprotein cholesterol, and triglyceride levels as screening tests for preventing coronary heart disease in adults. American College of Physicians. Part 1. Ann Intern Med 1996 Mar 1;124(5):515-7.
- U.S. Preventive Services Task Force. Screening for high blood cholesterol and other lipid abnormalities. In: Guide to clinical preventive services. 2nd ed; Baltimore (MD): Williams & Wilkins; 1996. p. 15-38.
- Pharmacy Benefits Management—Medical Advisory Panel. The pharmacologic management of hyperlipidemia. VHA PBM-SHG Publication. Hines (IL): Pharmacy Benefits Management Strategic Health Group, Veterans Health Administration, Department of Veterans Affairs, 1999.

DATE RELEASED

2001 Dec

GUIDELINE DEVELOPER(S)

Department of Defense - Federal Government Agency [U.S.]
Department of Veterans Affairs - Federal Government Agency [U.S.]
Veterans Health Administration - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Management of Dyslipidemia Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

Veterans Health Administration National Clinical Practice Guideline Council - Federal Government Agency [U.S.]

GUIDELINE STATUS

This is the current release of the guideline.

Note from Veteran Health Administration (VHA) and the National Guideline Clearinghouse (NGC): The drug Baycol (Cerivastatin) was withdrawn from the market. The guideline developer is currently working to update their guideline to reflect this drug withdrawal. NGC will publish an updated Summary as soon as the revised guideline is available. For more information on the withdrawal of this drug, please go to the FDA Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Veterans Health Administration (VHA) Web site.

Print copies: Available from the Department of Veterans Affairs, Veterans Health Administration (VHA), Office of Quality and Performance (10Q), 810 Vermont Ave. NW, Washington, DC 20420.

AVAILABILITY OF COMPANION DOCUMENTS

Various companion documents are available from the Veterans Health Administration (VHA) Web site.

In addition, the VHA Web site provides references to related guidelines, performance measures, and other resources.

Also available:

- Guideline for Guidelines. Draft. Washington (DC): Veterans Health Administration, Department of Veterans Affairs. Available at the Veterans Health Administration (VHA) Web site.

In addition, the guideline drew heavily from the following sources:

- Executive summary of the Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA 2001 May 16;285(19):2486-97.
- NIH Consensus conference. Triglyceride, high-density lipoprotein, and coronary heart disease. NIH Consensus Development Panel on Triglyceride, High-Density Lipoprotein, and Coronary Heart Disease. JAMA 1993 Jan 27;269(4):505-10.
- Guidelines for using serum cholesterol, high-density lipoprotein cholesterol, and triglyceride levels as screening tests for preventing coronary heart disease in adults. American College of Physicians. Part 1. Ann Intern Med 1996 Mar 1;124(5):515-7.
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- Pharmacy Benefits Management—Medical Advisory Panel. The pharmacologic management of hyperlipidemia. VHA PBM-SHG Publication. Hines (IL): Pharmacy Benefits Management Strategic Health Group, Veterans Health Administration, Department of Veterans Affairs, 1999.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 9, 2002. The information was verified by the guideline developer on September 25, 2002.

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